

# Increasing the Efficiency of Biosimilar Development Programs— Reevaluating the Need for Comparative Clinical Efficacy Studies

## Workshop Agenda

<b>Session 1 (Public):</b> <i>Setting the stage—How have we been using comparative clinical efficacy studies (CES) in biosimilar development programs, and what have we learned?</i> <b>Tuesday, September 12, 2023</b> <b>7:00 am – 10:00 am Eastern Time (US &amp; Canada); 1300 – 1600 Central European Time (CET)</b>	
<b>Welcome/Opening Remarks (10 min)</b>	Carol Kim and Brooke DalSanto, US FDA
<b>Regulatory Experience and Considerations to Date (110 min)</b>	Regulatory Agency Speakers <ul style="list-style-type: none"> <li>• Marie-Christine Bielsky, MHRA</li> <li>• Hye-Na Kang, WHO</li> <li>• Rene Anour, EMA</li> <li>• Bradley Scott, Health Canada</li> <li>• Ryosuke Kuribayashi, PMDA</li> <li>• Woo-Yong Oh, MFDS</li> <li>• Stacey Ricci, US FDA</li> </ul>
<b>Panel, Q&amp;A (50 min)</b>	Moderator: Ali Al Homaidan, SFDA
<b>Closing Remarks (10 min)</b>	Carol Kim, US FDA
<b>Session 2 (Public):</b> <i>Stakeholder perspectives on the need for CES in biosimilar development programs</i> <b>Wednesday, September 13, 2023</b> <b>7:00 am – 10:00 am Eastern Time (US &amp; Canada); 1300 – 1600 Central European Time (CET)</b>	
<b>Welcome Day 2 (5 min)</b>	Brooke DalSanto, US FDA
<b>Stakeholder Experience with and Perspectives on CES (120 min)</b>	Stakeholder Representative Speakers <ul style="list-style-type: none"> <li>• Martin Schiestl, Sandoz</li> <li>• Gillian Woollett, Samsung</li> <li>• Fabrice Romanet, Fresenius-Kabi</li> <li>• Keith Watson, KRW Bio Reg Solutions</li> <li>• Elena Wolff-Holz, Biocon</li> <li>• Elena Guillen, Hospital Clinic de Barcelona</li> <li>• Frank Schneider, Teva</li> </ul>
<b>Panel, Q&amp;A (45 min)</b>	Moderator: Steffen Thirstrup, EMA
<b>Closing Remarks (10 min)</b>	Sarah Yim, US FDA
<b>Session 3-5 (Regulators only):</b> <i>Regulatory considerations regarding efficient use of comparative clinical efficacy studies in biosimilar development programs</i> <b>Tuesday-Thursday, September 19-21, 2023</b> <b>7:00 am-10:00 am Eastern Time (US &amp; Canada); 1300 – 1600 Central European Time (CET)</b>	

